

R E M A R K S

Claims 1-18 and 31 are pending in the present application. The following rejections remaining at issue and are set forth by number in the order in which they are addressed:

1. Claims 1-18 are rejected under the judicially created doctrine of obviousness-type double patenting over claims 9-16 of U.S. Patent No. 6,015,833 in view of Cook et al. U.S. Patent No. 5,760,082; and
2. Claims 1-18 are rejected under 35 U.S.C. §103(a), as allegedly obvious over Cook et al. (U.S. Patent No. 5,760,082) in view of Cain et al. (WO97/18320) and Baltes et al. (U.S. 3,162,658) in further view of Nilsen et al. (U.S. 5,885,594); and

1. The Double Patenting Rejection Is Improper

Applicants contend that the double patenting rejection is not proper for the reasons stated in the prior Responses. Nevertheless, Applicants herein offer to submit a Terminal Disclaimer over the U.S. 6,015,833 upon the Examiner's indication of patentable subject matter in the instant application.

2. The Examiner Has Failed to Establish a *Prima Facie* Case of Obviousness

Claims 1-18 and 31 are rejected under 35 U.S.C. §103(a) as allegedly being obvious under Cook et al. (U.S. Patent No. 5,760,082) in view of Cain et al. (WO97/18320) and Baltes et al. (U.S. 3,162,658) in further view of Nilsen et al. (U.S. 5,885,594). Applicants must again respectfully disagree.

A *prima facie* case of obviousness requires the Examiner to cite a reference, or combination of references, that (a) discloses all of the elements of the claimed invention, (b) provides a suggestion or motivation to one of skill in the art to combine the elements to yield the claimed combination, and (c) provides a reasonable expectation of successfully carrying out the claimed combination. Failure to establish any one of the three requirements precludes a finding of a *prima facie* case of obviousness, and, without more, entitles the Applicants to allowance of the claims at issue.¹ In addressing this rejection, Applicants focus on the independent claims since the non-obviousness of independent claims necessarily leads to the non-obviousness of the

¹ See, e.g., *Northern Telecom Inc. v. Datapoint Corp.*, 15 USPQ2d 1321, 1323 (Fed. Cir. 1990).

claims dependent thereon.²

The Examiner has failed to provide suitable evidence of a motivation to combine the cited references, thus a *prima facie* case of obviousness has not been established. The Examiner has combined three references, Cook (U.S. pat. No. 5,760,092), Cain (WO 97/18320), and Baltes (U.S. Pat. No. 3,162,658).

In Paragraph 5 of the Office Action, the Examiner states that Cook teaches a food product containing conjugated linoleic acids, their esters, salts or mixtures. In Paragraph 6, the Examiner admits that Cook does not teach the use of alcoholic catalysts for isomerization. In Paragraph 7, the Examiner then states that Cain teaches that it is well known to use anti-oxidants in food products containing CLA. Additionally, the Examiner states that Baltes teaches that isomerization of linoleic acid compounds with alcoholate catalysts is well known.

The Examiner then provides the following statement regarding motivation to combine the cited references:

A person of ordinary skill in the art would have been motivated to employ alcoholate catalyst, such as potassium methylate, for isomerization of linoleic acid acid to obtain CLA, or to incorporate conjugated linoleic acid derivatives, including esters, as well as antioxidants in a food product, wherein the CLA is free of volatile organic compounds and free of oxidation because alcoholate catalysts, such as potassium methylate, are **well-known to be useful** for isomerization of linoleic acid to CLA, and CLA is known to be sensitive to oxidation and antioxidant are known to be useful along with conjugated linoleic acid compounds in food products. Regarding the limitation about the method to obtain the conjugated linoleic acid, note a method of making ingredients is not seen to render patentable weight to a method which employs such ingredients, absent evidence to the contrary. It is particularly truth if the method of making the ingredients is a **well-known process**, e.g., employ alkali monohydric alcoholate for making conjugated linoleic acid. A process of making a composition by simply combining or mixing the known ingredients is seen to be within the skill of the artisan. (Emphasis added).

Applicants respectfully submit that the Examiner's reasoning regarding motivation to combine is flawed at several levels: a) the Examiner's statements are conclusory; b) the Examiner has applied hindsight reconstruction; and c) the Examiner has ignored evidence presented by the Applicants establishes that patentable weight should be given to the combination of adding

² §MPEP 2143.03.

alcoholate catalyzed CLA to food products. For these reasons, discussed in detail below, the Examiner has not established a proper basis for combining the references and thus has not established a *prima facie* case of obviousness.

a) The Examiner's statements are conclusory

The Examiner's reasoning regarding motivation to combine quoted above relies solely on the Examiner's conclusion that the various elements of the invention were "well-known." The Examiner's reasoning is conclusory because it merely recites the references and says that they can be combined to produce the claimed results because the individual elements are "well-known." The Federal Circuit has expressly forbidden this approach. Specifically, the Federal Circuit has held that:

The factual inquiry whether to combine references must be thorough and searching. It must be based on **objective evidence** of record. **This precedent has been reinforced in myriad decisions, and cannot be dispensed with.**

See, In re Lee, 277 F.3d 1338, 1344 (Fed. Cir. 2002); internal citations omitted; emphasis added. Indeed, the Federal Circuit has made it clear that "[b]road, **conclusory** statements regarding the teachings of multiple references, standing alone, are not 'evidence.'" *In re Dembicza*k, 175 F.3d 994, 50 USPQ2d 1614 (Fed. Cir. 1999)(emphasis added).

Thus, the Examiner's conclusory motivation statement falls well short of the standards established by the Federal Circuit. In particular, the Examiner has provided no objective evidence of why a person of skill in the art would combine the references other than the fact that the elements are allegedly well-known. The Examiner has not provided any reference to a suggestion in the references themselves or in the art as to why the references should be combined, regardless of whether the individual elements are allegedly well known.

In response to Applicants previous arguments regarding motivation to combine, the Examiner states that Baltes suggests the claimed invention because Baltes states that "it will be understood that the process of this invention is broadly applicable to any unconjugated polyethenoid acid compounds and products containing them." The Examiner takes this statement completely out of context. As pointed out in the Declaration of Asgeir Sæbo (discussed in more detail below), Baltes teaches the use of alcoholate catalysts to produce CLA for use in industrial products such as paints and varnishes. Baltes fails to address the use of CLA made by these

methods in food products. Thus, a person of ordinary skill in the art reading Baltes would interpret the statement quoted by the Examiner as teaching that the processes of Baltes could be used to produce CLA for use in industrial type products, not food products. As such, this so-called "suggestion" from Baltes cannot serve as motivation to combine the references.

b) The Examiner has applied hindsight reconstruction

In addition to substituting conclusory statements for the required objective evidence of motivation to combine, the Examiner has applied hindsight reconstruction to combine the references. The Federal Circuit expressly forbids this approach:

The Board did not . . . explain what specific understanding or technological principal within the knowledge of one of ordinary skill in the art would have suggested the combination. **Instead, the Board merely invoked the high level of skill in the art.** If such a rote invocation could suffice to supply a motivation to combine, the more sophisticated scientific fields would rarely, if ever, experience a patentable technological advance. Instead, in complex scientific fields, the Board could routinely identify the prior art elements in an application, invoke the lofty level of skill, and rest its case for rejection. To counter this potential weakness in the obviousness construct, the suggestion to combine requirement stands as a critical safeguard against hindsight analysis and rote application of the legal test for obviousness (Emphasis added).

In re Rouffet, 47 USPQ2d 1453 (Fed. Cir. 1998).

In the instant application, the Examiner relies on what is allegedly "well known" to those of skill in the art as basis for combining the references. This is nothing more than invoking a high level of skill in the art. The Examiner has provided no objective evidence of why just because the individual elements are allegedly "well known," a person of ordinary skill in the art would be motivated to combine the references. Since no other rationale is provided, it is apparent that the combination only becomes obvious once the specification of the instant application has been consulted. Thus, it appears that the Examiner has impermissibly applied hindsight reconstruction.

c) The Examiner has ignored evidence presented by the Applicants that establishes that patentable weight should be given to the combination of adding alcoholate catalyzed CLA to food products.

The Examiner states that "[R]egarding the limitation about the method to obtain the conjugated linoleic acid, note a method of making ingredients is not seen to render patentable weight to a method which employs such ingredients, absent evidence to the contrary."

Applicants first note that this statement ignores the actual language of the claims, which specify the particular step of using an alcoholate catalyst. This is contrary to the Examiner's statement that the claims only employ such ingredients. Applicants fail to see how the Examiner can simply ignore a process step and reason that a specific step cannot provide patentable weight to a method claim. If the Examiner is aware of any legal authority on this point, the Examiner is urged to provide it. Applicants are not aware of any such legal precedent.

Furthermore, Applicants **have provided** evidence that it is not obvious to simply use a process that was previously used for the production of CLA for industrial uses with a method for food production. This evidence is provided by the Declaration of Asgeir Sæbo. As detailed in the Sæbo Declaration, none of the references teach or suggest using CLA isomerized with alcoholate catalysts in food products. Furthermore, as explained by Dr. Sæbo, the Baltes patent discloses the use of oils with high levels of triunsaturated fatty acids. These oils are not generally suitable for the production CLA for oral consumption. Thus, the Examiner's attempt to claim that the compositions of Baltes could be used in a food product is misguided. In fact, the Baltes reference indicates that the uses the products are suited for are industrial in nature. In particular, Baltes et al. describe methods for producing conjugated linoleic acids described as being "valuable industrial products" for use in formation of "light colored polymers," for use as "ingredients of lacquers or coating compositions" or as "ingredients of plasticizers" and as "reaction components in the preparation of resins" (Baltes et al., col. 9, ll. 47-60). As such, the Baltes reference is directed to the production of substitutes for tung oil that are not suitable for consumption. The tung oil substitutes described in Baltes et al., are intended for industrial uses such as for drying oils, varnishes, and lacquers. Consequently, Baltes et al., describes methods for producing toxic oil substitutes for non toxic oils (tung oil). Nothing in the Baltes et al. reference teaches or suggest the desirability--or even applicability--of using the methods disclosed therein to produce food products.

Thus, Applicants **have provided evidence** as to why a method that uses CLA produced by alcoholate catalysis to make food products is non-obvious. It should be noted that the failure of the Examiner to properly consider the Sæbo Declaration is grounds for reversal by The Board of Patents Appeals and Interferences should this case be appealed. The Examiner must respond to all of the arguments and evidence presented by Applicants. The MPEP states that:

Office personnel should consider all rebuttal arguments and evidence presented by applicants. . . . *In re Beattie*, 974 F.2d 1309, 1313, 24 USPQ2d 1040, 1042-43 (Fed. Cir. 1992). . . . Office personnel should avoid giving evidence no weight, except in rare circumstances. *Id. See also In re Alton*, 76 F.3d 1168, 1174-75, 37 USPQ2d 1578, 1582-83 (Fed. Cir. 1996).

* * *

A determination under 35 U.S.C. 103 should rest on **all the evidence** and should not be influenced by any earlier conclusion. *See, e.g., Piasecki*, 745 F.2d at 1472-73, 223 USPQ at 788; *In re Eli Lilly & Co.*, 902 F.2d 943, 945, 14 USPQ2d 1741, 1743 (Fed. Cir. 1990). Thus, once the applicant has presented rebuttal evidence, Office personnel should **reconsider** any initial obviousness determination in view of the entire record. *See, e.g., Piasecki*, 745 F.2d at 1472, 223 USPQ at 788; *Eli Lilly*, 902 F.2d at 945, 14 USPQ2d at 1743.³

Additionally, the Courts have held as follows:

When *prima facie* obviousness is established and evidence is submitted in rebuttal, the decision-maker must start over . . . An earlier decision should not . . . be considered as set in concrete, and applicant's rebuttal evidence then be evaluated only its knockdown ability. Analytical fixation on an earlier decision can tend to provide the decision with an undeservedly broadened umbrella effect. *Prima facie* obviousness is a legal conclusion, not a fact. Facts established by rebuttal evidence must be evaluated along with the facts on which the earlier conclusion was reached, not against the conclusion itself. Though the tribunal must begin anew, a final finding of obviousness may of course be reached, but such finding will rest upon evaluation of all facts in evidence, uninfluenced by any earlier conclusion reached . . . upon a different record.⁴

Furthermore:

If a *prima facie* case is made in the first instance, and if the applicant comes forward with a reasonable rebuttal, whether buttressed by experiment, prior art references, or argument, the entire merits of the matter are to be reweighed.⁵

Accordingly, even if the Examiner had established a *prima facie* of obviousness in the preceding office action (and Applicants contend that he did not), the Examiner must respond to Applicants arguments.

For the reasons stated above, Applicants respectfully submit that a *prima facie* case of obviousness has not been established and therefore respectfully request that this rejection be withdrawn.

C O N C L U S I O N

All grounds of rejection and objection of the Office Action of July 16, 2003 having been

³ MPEP §§2144.08; emphasis added).

⁴ *In re Rinehart*, 531 F.2d 1048, 1052, 189 USPQ 143, 147 (CCPA 1976).

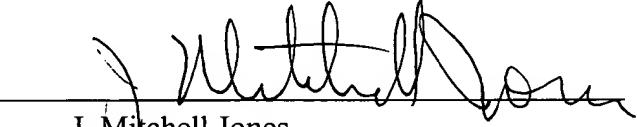
⁵ *In re Hedges*, 783 F.2d 1038, 1039, 228 USPQ 685, 686 (Fed. Cir. 1986).

PATENT

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addressed, reconsideration of the application is respectfully requested. It is respectfully submitted that the invention as claimed fully meets all requirements and that the claims are worthy of allowance. Should the Examiner believe that a telephone interview would aid in the prosecution of this application, Applicant encourages the Examiner to call the undersigned collect at (608) 218-6900.

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